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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,683	06/06/2003	Michael Albert Strobel	101918.56959C1	1628

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EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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06/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,683	Applicant(s) STROBEL, MICHAEL ALBERT	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,10-12 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10-12 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 16-17 are objected to because of the following informalities:

The use of the trademark Tween 80 has been noted in claims 16-17. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (U.S. Patent No. 5,773,422) in view of Huet et al (U.S. Patent No. 6,482,425).

Komer disclose a pharmaceutical formulation comprising ivermectin, propylene glycol and polysorbate 80 and benzyl alcohol.(Example 17, column 6) but does not disclose the addition of ethanol or isopropanol. However, since Huet et al teach that benzyl alcohol, ethanol and isopropanol can interchangeably be used in ivermectin containing compositions (column 5, lines 56-58, column 6, lines 66-67 and column 7, line 1), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to substituted ethanol or isopropanol for benzyl alcohol in a composition disclosed by Komer because such a person would have expected the resulting composition to retain its properties.

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive.

It has been noted that the present claims have been limited to the terminology "consisring essentially of". Note that the terminology "consisting essentially of" limits the scope of the claims to the specified materials or steps and "those that do not materially affect the basic and novel characteristic(s)" of the claimed invention (MPEP 211.03). In the present case, applicant has failed to show that N-methylpyrrolidone disclosed by

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Komer would materially affect the basic and novel characteristic(s) of the claimed solution.

Claims 10-12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (U.S. Patent No. 5,772,422).

Komer discloses a formulation comprising ivermectin, propylene glycol and posysorbate 80 (Examples 14 and 17) and a process for preparing said formulations (column 3, lines 6-45) but do not disclose the amounts of propylene glycol and polysorbate 80 encompassed by the present claims. However, a person having ordinary skill in the art at the time the present invention was made would have been motivated to add additional amounts of propylene glycol and polysorbate 80 to the reference's composition without adversely affecting the properties of said composition.

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive.

It has been noted that the solutions disclosed by Komer include N-methylpyrrolidone or 2-pyrrolidone. However, applicant has not provided any evidence that N-methylpyrrolidone or 2-pyrrolidone would materially affect the basic and novel characteristic(s) of the claimed invention.

Claims 17, 18, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (U.S. Patent No. 5,773,422) in view of Lacy et al (U.S. Patent No. 5,645,856).

Komer discloses an ivermectin containing composition for oral use (Example 17, column 6) and a method for forming said composition but does not disclose the addition of a sweetening agent. However, since the addition of a sweetening agent to a pharmaceutical composition was well known in the art at the time of the present invention as disclosed by Lacy et al (column 14, lines 2-3), a person having ordinary skill in the art at the time the present invention was made would have been motivated to add a sweetening agent to a composition disclosed by Komer in order to improve the flavor of said composition.

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive.

Applicant contends that the claimed methods do not include using either N-methylpyrrolidone or 2-pyrrolidone. This argument has not been found persuasive.

Komer discloses that ivermectin formulations including N-methylpyrrolidone or 2-pyrrolidone have advantage of providing higher concentrations of ivermectin, improved stability and less pain, swelling and tissue damage at the injection site (column 2, lines 4756) i.e. Komer suggests that the use of N-methylpyrrolidone or 2-pyrrolidone is desirable for injectable formulations. However, it is clear from the teachings by Komer that the addition of N-methylpyrrolidone or 2-pyrrolidone to ivermectin preparations which are already water soluble, stable and not intended to be injected not necessary

Claims 19-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Komer (U.S. Patent No. 5,773,422).

Komer discloses a pharmaceutical composition comprising ivermectin, propylene glycol and polysorbate 80 (Examples 14 and 17). The claimed compositions are anticipated by Komer. In addition, if there are differences in amounts of the components present, such differences would appear to be minor in nature, and the claimed compositions, which fall within the scope of the prior art's compositions, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive.

Applicant contends that Komer's statement of the unexpected solubility of avermectin in N-methylpyrrolidone demonstrates that one of skill in the art would expect N-methylpyrrolidone to affect the basic and novel characteristics of the claimed invention. This argument has not been found persuasive. The believe by one skilled in the art is not evidence. Further, the present claims are directed to water soluble concentrates. Therefore, the addition of N-methylpyrrolidone, which affects the solubility of ivermectin , to an already soluble preparation would not be expected to change the novel characteristics of said preparation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

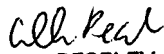
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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